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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,010	08/09/2006	Kenichiro Kosai	55801-002US1	9188

69713 7590 09/02/2010

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/567,010	KOSAI ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-51* is/are pending in the application.

4a) Of the above claim(s) *42,50 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18-41, 43-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 42, 50 and 51 fail to comply with PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 42, 50 and 51 are indefinite for the following reason(s):

Claims 42, 50 and 51 provide for the use of certain adenoviral vectors in methods of treatment, but, since the claims do not set forth any active steps involved in the methods, it is unclear what methods applicant are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Furthermore, "use claims" are considered non-statutory under US patent practice. See MPEP § 2173.05 Therefore, the claims cannot be evaluated for restriction purposes and the claims have not been further treated on the merits.

Any amended claims will be treated as newly presented claims in the next Office Action. It will be determined at that time if they read on the elected invention.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 18-37, drawn to methods of preparing proliferation-regulated adenoviral vectors by preparing vectors comprising an adenoviral E1 region under the control of target organ-specific promoters, a poly(A) sequence, and a recombinase recognition site followed by insertion of the proliferation regulating unit into an adenoviral genome lacking the E1 region.

Group II, claim(s) 38, drawn to a plasmid having a proliferation regulating unit.

Group III, claim(s) 39, drawn to a preparative kit comprising a plasmid having a proliferation regulating unit and a plasmid having an E1-deficient adenoviral genome.

Group IV, claim(s) 40 and 48, drawn to a preparative kit comprising a plasmid having a proliferation regulating unit, a plasmid having an E1-deficient adenoviral genome, and a plasmid having a therapeutic gene expressing unit.

Group V, claim(s) 41 and 49, drawn to a plasmid having a therapeutic gene expressing unit.

Group VI, claim(s) 43-47, drawn to a recombinant adenoviral (sic) comprising exogenous promoters replacing the E1 endogenous promoters, and an exogenous gene.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

None of Groups II-VI require the special technical feature of Group I, which is preparing a vector comprising an adenoviral E1 region under the control of target organ-specific promoters, a poly(A) sequence, and a recombinase recognition site (specifically, the location of the recombinase site is the feature that defines the invention of Group I over the prior art). All of the inventions recited in Groups II-V are limited by intended use language, i.e. plasmids "for use in the method" of Group I. Thus, the claimed products are not limited by the recited method step and thus do not require a recombinase site because prior art plasmids not having a recombinase site could certainly be used as templates for "preparing" the plasmids as recited in claim 18. The product of Group VI is not recited as being prepared by the methods of Group I and thus does not share a special technical feature with Group I, as the claimed adenovirus could be made using other methods not requiring use of a recombinase site (see the plasmids of Yu et al below).

The technical feature(s) linking Groups II-VI are the various plasmids recited in the claims. However, Yu et al (US 6,692,736) discloses numerous plasmids including "proliferation regulating units" comprising adenoviral E1 genes under control of exogenous promoters, some of which also include a therapeutic gene. In particular see Figures 5 and 7. Such plasmids could be used as a starting point or source material in the methods of Group I for preparing the vectors recited in claim 18. Regarding Groups III and IV, an E1-deficient adenoviral genome is taught by Mizuguchi et al, se Fig. 1 (H. Gene Ther., 1998).

Therefore, the technical feature(s) linking the inventions of Groups II and VI do not constitute a special technical feature as defined by PCT Rule 13.2, as they do not define a contribution over the prior art.

The special technical feature of Group I is considered to be methods of preparing proliferation-regulated adenoviral vectors by preparing vectors comprising an adenoviral E1 region under the control of target organ-specific promoters, a poly(A) sequence, and a recombinase recognition site, a special technical feature not shared by the other Groups.

The technical feature of Group II is considered to be a plasmid having a proliferation regulating unit, a feature not shared with Groups I and V.

The special technical feature of Group III is considered to be preparative kit comprising a plasmid having a proliferation regulating unit and a plasmid having an E1-deficient adenoviral genome, a feature not shared with Groups I, V and VI.

The special technical feature of Group IV is considered to be a preparative kit comprising a plasmid having a proliferation regulating unit, a plasmid having an E1-deficient adenoviral genome, and a plasmid having a therapeutic gene expressing unit, a feature not shared with Groups I and VI.

The special technical feature of Group V is considered to be a plasmid having a therapeutic gene expressing unit, a feature not shared with Group I-III and VI.

The special technical feature of Group VI is considered to be a recombinant adenoviral (sic) comprising exogenous promoters replacing the E1 endogenous promoters, and an exogenous gene, a feature not shared with the other Groups.

Accordingly, Groups I-VI are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633